Patent Application Docket No. PC9942C

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of person mailing) Kelly A. Smith

(Typed or printed name of person)

TECHOEN 2 3 2003 IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Charles K. Chiu and

Lewin T. Wint

Serial No.:

10/087,756

Filed: March 4, 2002

Group Art Unit: 1625

Examiner: ROBINSON, Binta

For: A PROCESS FOR PREPARING

NAPHTHYRIDONES AND

INTERMEDIATES

12/17/2003 MDANTE1 00000121 161445 10087756

BRIEF ON APPEAL

330.00 DA 01 FC:1402

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

By Notice of Appeal, filed August 11, 2003, Appellants have appealed the Final Rejection, dated July 9, 2003, of

PTO/SB/17(01/03)
Approved for use through 04/30/2003. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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				First Named Inventor			March 4, 2002 Charles K. Chiu Binta Robinson 1625			
Effective 01/01/2003. Patent fees are subject to annual revision.				Examiner Name			Binta Robinson	CEAN		0
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The Commissioner is authorized to: (check all that apply)			1052	50	2052		Surcharge-late provisional filing fee or cover sheet			
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Name (Printed/Type) Scott Alexander McNeil							Reg. Number 37,185			
Signature Str 100 1 100 1				12/1	1/03		Telephone	(860)686-184	8	- 1

Claims 8-11. Appellants submit this Brief, in triplicate, to support the Notice of Appeal.

Payment authorization, for filing this Brief On Appeal, is provided by the concurrently filed Transmittal Letter.

A request for a two-month extension of time, and the authorization for payment of the appropriate fee, is separately enclosed herewith.

I. Real Party in Interest

The present application, listing the Charles K. Chiu and Lewin T. Wint, is owned in its entirety by Pfizer Inc.

II. Related Appeals and Interferences

There are no other appeals or interferences, known to Appellants or Appellants' Attorney, relating to the present application, which will directly affect, be directly affected by, or have a bearing on the Board's decision on the pending appeal.

III. Status of Claims

Claims 8-11 are currently pending in the present application. Claims 8-11, which are attached as Appendix A, are final rejected under 35 USC 112, first paragraph. Claim 8 also stands final rejected under 35 USC 112, second paragraph.

IV. Status of Amendments

No amendments have been filed in the present application subsequent to the final rejection.

V. Summary of the Invention

The present invention, as claimed in independent Claim 8, is directed to a method for making a compound having the structure of Formula IV, shown below.

$$\begin{array}{c|c} O & H & CO_2R^3 \\ \hline O & H & N & N \\ \hline R^2CHN & H & F \\ \hline \end{array}$$

wherein R^2 is C_1 - C_6 alkyl, trifluoromethyl, or phenyl which may be substituted by one or more of C_1 - C_6 alkyl, C_1 - C_6 alkoxy, halo, nitro, amino or trifluoromethyl.

The invention of Claim 11 is directed to a compound of Formula VI.

VI. Issues

- A. Whether Claims 8-11 are properly rejected under 35 USC 112, first paragraph.
- B. Whether Claim 8 is properly rejected under 35 USC 112, second paragraph.

VII. Grouping of Claims

Claims 8-11 are one group. It is respectfully requested that the Board select Claim 8 to decide the appeal as to the grounds of the rejection of Claims 8-11.

VIII. Argument

A. A Rejection, Under 35 USC 112, First Paragraph, for not Enabling One Skilled in the Art to Make a Compound Having 3 or More Nitro or Amino Groups on a Phenyl Ring, Is Not Proper

Claims 8-11 are rejected under 35 USC §112, first paragraph, as not enabling one skilled in the art to make the invention. The Examiner states that while the Specification provides enablement for R² equaling 1 to 2 nitro, or amine, groups on the phenyl in a meta position, the Specification does not provide enablement for a phenyl R² group that is substituted 3 or more times with nitro or amino groups. Further, the Examiner states, without providing any basis of support, that no compound has ever been synthesized where a phenyl ring can support electron-withdrawing groups, such as nitro, in the ortho position.

Contrary to the Examiner's statement, the Specification does enable one of skill in the art to make and use the invention of Claims 8-11.

The purpose of the enablement provision is to assure that the inventor provides sufficient information about the claimed invention so that a person of skill in the art can make and use it without undue experimentation relying on the Specification and the knowledge in the art. (See Scripps Clinic & Research Foundation v. Genentech, Inc., 18 USPQ2d 1896 (Fed. Cir. 1991).)

Contrary to the Examiner's statement, phenyl compounds, and processes, are know in the art for producing phenyl compounds that (1) are substituted at the ortho position with a nitro or amino group, and (2) are substituted 3 or more times with nitro and amino groups. Numerous examples

of such compounds are present in the American Chemical Society registry of compounds. In demonstration of this fact, 19 different structures, from the ACS Registry, are attached, in Appendix B, which show compounds containing phenyl groups that are substituted at the ortho position with a nitro or amine group and compounds containing phenyl groups that are substituted 3 or more times with nitro or amine groups. Thus, utilizing the known methods in the art for making these compounds, one of skill in the art would be able, without undue experimentation, to make compounds of Claims 8-11 wherein the R² group is a phenyl that is substituted at the ortho position and/or 3 or more times with nitro or amino groups.

Thus, pending Claims 8-11 are improperly rejected as being non-enabling.

B. A Rejection, Under 35 USC 112, Second Paragraph, for Being Indefinite in that the Phrase "One or More" is Indefinite and as a Phenyl Ring Cannot Support Electron-Withdrawing Groups in the Ortho Position, Is Not Proper

The Examiner states that, in Claim 8, the phrase "one or more C_1 - C_6 alkyl, C_1 - C_6 alkoxy, halo, nitro, amino or trifluoromethyl" is indefinite as there is no upper bound on the phrase "one or more".

Contrary to the Examiner's statement, the phrase "one or more" is not indefinite.

It is not required that an application describe claim limitations in detail greater than the invention warrants. (See Martin v. Mayer, 3 USPQ2d 1333 (Fed. Cir. 1987).) Rather, the application only needs description sufficient that it conveys to those skilled in the art that the

applicant has invented the subject matter claimed. (See In re Kaslow, 217 USPQ 1089, 1096 (Fed. Cir. 1983).)

In Claim 8, the phrase "one or more C_1 - C_6 alkyl, C_1 - C_6 alkoxy, halo, nitro, amino or trifluoromethyl" relates to possible substitution of the group R^2 wherein R^2 can be a C_1 - C_6 alkyl, trifluoromethyl or phenyl. It is well within the knowledge of one skilled in the art how many times a methyl, ethyl, propyl, butyl, pentyl, hexyl, trifluoromethyl or phenyl group may be substituted with one of the above-identified substituents. Therefore, based upon the disclosure provided in the present Application, does sufficiently describe to a skilled artisan the scope of the presently claimed invention.

Further, phrases such as "one or more" or "at least one", as used in chemical claims, are clearly understood by the skilled artisan. The clear understanding and acceptance of such claim language, by the skilled artisan, is further demonstrated by US Patent No. 5,684,135 (Claim 1), US Patent No. 5,653,960 (Claim 1), and US Patent No. 5,532,242 (Claim 1).

The Examiner also made the baseless assertion that a phenyl ring cannot support an electron-withdrawing group, such as nitro, in the ortho position.

As previously described herein, in the response to the Examiner's rejection under 35 USC §112, first paragraph, the Examiner's statement is incorrect.

Thus, pending Claim 8 is improperly rejected as being indefinite under 35 USC 112, second paragraph.

IX. Conclusion

In view of the above information, present Claims 8-11 are not properly rejected under 35 USC 112, first or second

paragraphs. Therefore, it is respectfully requested that the rejections of Claims 8-11 be withdrawn and that Claims 8-11 be allowed.

Date: 11 December 2003

Respectfully submitted,

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APPENDIX A

CLAIMS UNDER APPEAL

8. A process for the preparation of a compound of the formula

wherein R^2 is C_1 - C_6 alkyl, trifluoromethyl, or phenyl which may be substituted by one or more of C_1 - C_6 alkyl, C_1 - C_6 alkoxy, halo, nitro, amino or trifluoromethyl, and

 $\mbox{\ensuremath{R}^3}$ is $\mbox{\ensuremath{C_{1}\text{-}}\mbox{\ensuremath{C_{6}}}}$ alkyl, which comprises reacting a compound of the formula

$$CI$$
 N
 CO_2R^3
 V

with a compound of the formula

9. A process comprising hydrolysis of the compound of formula VI with methanesulfonic acid, water and an organic solvent to form a monomethanesulfonic acid salt of a compound of the formula

$$H_2N$$
 H
 H
 N
 N
 N
 N
 F
 F

10. A process comprising hydrolysis of the compound of formula VI with methanesulfonic acid and $\rm R^3OH$ wherein $\rm R^3$ is $\rm C_1\text{--}C_6$ alkyl to form a monomethanesulfonic acid salt of a compound of the formula

11. A compound of the formula

wherein

 $$\rm R^2$$ is $C_1\text{--}C_6$ alkyl, trifluoromethyl, or phenyl which may be substituted by one or more of $C_1\text{--}C_6$ alkyl, $C_1\text{--}C_6$ alkoxy, halo, nitro, amino or trifluoromethyl, and $$\rm R^3$$ is $C_1\text{--}C_6$ alkyl.

APPENDIX B

466685-30-3

$$\begin{array}{c|c} & \text{OMe} \\ & \text{NO2} & \text{OMe} \\ & \text{N} & \text{S} \\ & \text{N} & \text{SMe} \\ \\ & \text{O2N} & \\ \end{array}$$

Commercial Sources

No R f rences

68507-75-5

~1 Reference

476634-00-1

No R ferences
REGISTRY (Copyright 2003 ACS)

476307-07-0

No References
REGISTRY (Copyright 2003 ACS)

481053-41-2

~1 R ference REGISTRY (Copyright 2003 ACS) 29 January 2003

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473734-52-0

~1 Reference REGISTRY (Copyright 2003 ACS) 229342-59-0

~2 References
REGISTRY (Copyright 2003 ACS)

29 January 2003

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449747-91-5

$$_{\rm H_2N}^{\rm NH_2}$$
 Me

~1 Reference REGISTRY (Copyright 2003 ACS) 30226-35-8

No References
REGISTRY (Copyright 2003 ACS)

441787-12-8

~1 Reference

162247-02-1

$$O_2$$
 O_2 O_2 O_2 O_3 O_4 O_4 O_4 O_5 O_5 O_5 O_6 O_7 O_8 O_8 O_9 O_9

~1 Ref rence REGISTRY (Copyright 2003 ACS) 360779-11-9

~1 Reference

103025-39-4

~2 Ref rences
REGISTRY (Copyright 2003 ACS)

103025-38-3

~2 Ref rences
REGISTRY (Copyright 2003 ACS)

101410-95-1

$$0 \\ N = 0$$

~1 Reference

91125-10-9

~4 References

84432-53-1

$$0 \longrightarrow N \longrightarrow 0$$

$$Me$$

$$Me$$

$$N \longrightarrow 0$$

$$N \longrightarrow 0$$

$$N \longrightarrow 0$$

~9 References

29 January 2003

SciFinder

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360779-11-9

$$\begin{array}{c|c}
 & \text{NH 2} \\
 & \text{NH_2} \\
 & \text{NH_2} \\
 & \text{Me} \\
 & \text{O}
\end{array}$$

~1 Reference

18128-07-9

$$\begin{array}{c} \text{NH 2} \\ \text{H}_2 \text{N} \\ \\ \text{NH 2} \\ \\ \text{NH 2} \\ \end{array}$$

• 4 HCl

No References